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HELEN FOULK

IN THE UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF WISCONSIN

HELEN FOULK,

Plaintiff,

vs.

JOHNSON & JOHNSON, and ETHICON, INC.,

Defendants.
_____/

CASE NO:

COMPLAINT AND JURY DEMAND

Plaintiff Helen Foulk by and through her attorneys, Dunken Law Group, PLLC, brings this Complaint and Jury Demand against Defendants and alleges the following based upon personal knowledge, information and belief and investigation of counsel.

NATURE OF ACTION

1. This action seeks to recover damages for injuries sustained by Plaintiff as the direct and proximate result of the wrongful conduct of Defendants in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting and selling of transvaginal mesh.

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PARTIES

2. Plaintiff, Helen Foulk, is and was at all times alleged herein, a citizen and resident of Wisconsin. Plaintiff has suffered damages as a result of Defendants' illegal and wrongful conduct alleged herein.

3. Defendant, Johnson & Johnson, Inc. is a corporation, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair products. For diversity purposes, Johnson & Johnson is a citizen of New Jersey.

4. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson with its principal place of business located in Somerville, New Jersey. For diversity purposes, Ethicon is a citizen of New Jersey.

JURISDICTION AND VENUE

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

6. Venue in this action is proper pursuant to 28 U.S.C. § 1391(a) and (c), as a substantial number of the events, actions, and omissions giving rise to Plaintiff's claims occurred in this district. At all times material hereto, Defendants were for profit corporations authorized to and doing substantial business in the state of Wisconsin.

7. At all times alleged herein, Ethicon, Inc. included and includes any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint ventures, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. Defendant Ethicon, Inc. develops technology to diagnose and treat conditions related to the pelvic health of women.

9. At all times relevant herein, Ethicon, Inc. was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, packaging, labeling, and selling such devices, including the Gynecare TVT™ Obturator System. Ethicon manufactures, markets, advertises, promotes, and sells the Gynecare TVT™ Obturator System worldwide.

10. At all times relevant herein, Ethicon, Inc. designed and manufactured the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff, Helen Foulk, which gives rise to the Plaintiff's claims asserted herein.

11. At all times relevant herein, Ethicon, Inc. packaged the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

12. At all times relevant herein, Ethicon, Inc. labeled the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

13. At all times relevant herein, Ethicon, Inc. sold the Gynecare TVT™ Obturator System products throughout the United States, including the state of Wisconsin.

14. This is an action for damages in excess of $75,000, exclusive of interest, costs and attorneys' fees. Subject matter jurisdiction is proper pursuant to 28 U.S.C. § 1332.

15. Defendants are registered to transact business in the state of Wisconsin.

16. Defendants have transacted business within the state of Wisconsin and this Court has personal jurisdiction over Defendants under the Wisconsin Long-Arm Statute, *Wis. Stat. § 801.05.*

17. Defendants have committed a tortious injury in the state of Wisconsin caused by their acts and/or omissions outside of this state and they are subject to jurisdiction in this Court under the Wisconsin Long-Arm Statute, *Wis. Stat. § 801.05,* by virtue of their regular conduct and solicitation of business in this state, their continued derivation of substantial revenue from goods used or consumed in Wisconsin, and based on their otherwise persistent course of conduct in Wisconsin.

18. Defendants have purposefully and systematically committed acts and consummated transactions in the state of Wisconsin from which they have derived and continue to derive substantial revenues, and they have otherwise committed purposeful actions in the state of Wisconsin which should have led them to reasonably anticipate being hauled into court in Wisconsin. Jurisdiction is proper in this Court with respect to Defendants.

19. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in the Western District of Wisconsin and venue is proper in the Western District of Wisconsin under 28 U.S.C. § 1391 (a) and (c).

FACTUAL BACKGROUND

20. Plaintiff, Helen Foulk was implanted with a Gynecare TVT™ Obturator System product, Device No. 810081, Lot No. 3839463, during surgery performed by Rhea Rodgers, M.D. at the Surgicare of Wichita, Wichita, Kansas on or about August 7, 2015.

22. Plaintiff had a revision surgery for release of the Gynecare TVT™ Obturator System product by Kevin Miller, M.D. at the Surgicare of Wichita, Wichita, Kansas on or about January 11, 2016.

24. Defendant Ethicon, Inc. at all times material hereto, manufactured the Gynecare TVT™ Obturator System product.

25. The Gynecare TVT™ Obturator System product was implanted in Plaintiff, Helen Foulk, to treat her for genuine stress urinary incontinence and other symptoms, the use for which the product was designed, marketed and sold.

26. Defendant Ethicon, Inc. at all times material hereto, was engaged in the business of placing medical devices in the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Gynecare TVT™ Obturator System product which was implanted in Plaintiff, Helen Foulk, which gives rise to the Plaintiff's claims asserted herein.

27. Defendant Ethicon, Inc. at all times material hereto designed the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

28. Defendant Ethicon, Inc. at all times material hereto marketed the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff, which gives rise to the Plaintiff's claims asserted herein.

29. Defendant Ethicon, Inc. at all times material hereto marketed the Gynecare TVT™ Obturator System products through television, print and internet advertising and by sending sales representatives throughout the United States and to the state of Wisconsin to promote the sale of the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff.

30. Defendant Ethicon, Inc. at all times material hereto packaged the Gynecare TVT™ Obturator System products, including that which was implanted in Plaintiff.

31. Defendant Ethicon, Inc. at all times material hereto labeled the Gynecare TVT™ Obturator System products by placing its name on the outside of the Gynecare TVT™ Obturator System's packaging.

32. Defendant Ethicon, Inc. at all times material hereto, labeled the Gynecare TVT™ Obturator System products by placing its name on the paper inside the Gynecare TVT™ Obturator System product's packaging.

33. Defendant Ethicon, Inc. at all times material hereto, sold the Gynecare TVT™ Obturator System products throughout the United States, including the state of Wisconsin.

34. Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act ("Section 510(k)") allows the marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 29, 1976.

35. A predicate device is one that the Food and Drug Administration ("FDA") has placed into one of three classification categories and "cleared" for marketing. These regulatory classification categories include Class I, Class II, and Class III medical devices.

36. Under Section 510(k), a manufacturer must provide a premarket notification that allows the FDA to determine whether the device is substantially equivalent to a predicate device.

37. Under Section 510(k), no formal review for safety or efficacy is required.

38. The Gynecare TVT™ Obturator System product manufactured by Ethicon, Inc. is considered a Class II medical device under the FDA's medical device regulatory classification system.

39. Prior to 2005 Defendants sought and obtained the FDA's approval to market the Gynecare TVT™ Obturator System product under Section 510(k).

40. Ethicon, Inc. was, or should have been, aware of the dangers inherent in Gynecare TVT™ Obturator System products generally, notwithstanding the fact that these products were "cleared" for sale by the FDA.

41. As a result of having the Gynecare TVT™ Obturator System product implanted in her, Plaintiff has experienced significant mental and physical pain, disability, suffering, has sustained permanent injury, and permanent and substantial physical deformity, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income, has endured impaired physical relations during intimacy, and other damages.

42. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare."

43. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain."

44. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

45. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

46. Contemporaneously with the Safety Communication, the FDA released a

publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

47. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

48. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

49. In its White Paper, the FDA advised doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

50. The FDA concluded its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

51. Defendants knew or should have known about the risks and complications identified in the FDA Safety Communication.

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52. Defendants knew or should have known that their products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

53. The scientific evidence shows that the material from which Defendants' products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the products, including Plaintiff.

54. This negative response promotes inflammation of the pelvic tissue and contributes

to the formation of severe adverse reactions to the mesh, such as those experienced by Plaintiff.

55. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." Defendants' products were unreasonably susceptible to degradation and fragmentation inside the body.

56. Defendants' products were unreasonably susceptible to shrinkage and contraction inside the body.

57. Defendants' products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subjected to prolonged tension inside the body.

58. Defendants' products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

59. Defendants omitted the risks, dangers, defects, and disadvantages of their products, and advertised, promoted, marketed, sold and distributed the products as safe medical devices when Defendants knew or should have known that the products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, in some patients, including Plaintiff's catastrophic injuries.

60. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, Defendants' products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

61. The specific nature of the products' defects includes, but is not limited to, the following:

a. the use of polypropylene and collagen material in the products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the products to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the products, including, but not limited to, the propensity of the products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the products for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. the inelasticity of the products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

g. the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of cross-linked collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions.

62. Defendants' products are also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

m. the products' propensities to contract, retract, and/or shrink inside the body;

n. the products' propensities for degradation, fragmentation and/or creep;

o. the products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

p. the rate and manner of mesh erosion or extrusion;

q. the risk of chronic inflammation resulting from the products;

r. the risk of chronic infections resulting from the products;

s. the risk of permanent vaginal or pelvic scarring as a result of the products;

t. the risk of recurrent, intractable pelvic pain and other pain resulting from the products;

u. the need for corrective or revision surgery to adjust or remove the products;

v. the severity of complications that could arise as a result of implantation of the products;

w. the hazards associated with the products;

x. the products' defects described herein;

y. treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible available alternatives;

z. treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible available alternatives;

aa. treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible available alternatives;

bb. use of the products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

cc. removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

dd. complete removal of the products may not be possible and may not result in complete resolution of the complications, including pain.

63. Defendants have underreported information about the propensity of the products to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the products through various means and media.

64. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the products.

65. Defendants failed to design and establish a safe, effective procedure for removal of the products, or to determine if a safe, effective procedure for removal of the products exists.

66. Feasible and suitable alternatives to the products have existed at all times relevant that do not present the same frequency or severity of risks as do the products.

67. The products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting

the devices, and trained the implanting physicians.

68. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the products and the aftercare of patients implanted with the products.

69. The product or products implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

70. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.

71. In many cases, including Plaintiff, women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

72. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the products implanted in the relevant Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the products.

73. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

74. At all relevant times herein, Defendants continued to promote the products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

75. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the products.

76. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the products.

77. The products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in light of Defendants' knowledge of lack of safety.

78. As a result of having the products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

CAUSES OF ACTION:

COUNT I: NEGLIGENCE

79. Paragraphs 1-78 of this Complaint are hereby incorporated by reference as fully set forth herein.

80. Defendants had a duty to individuals, including Plaintiff, Helen Foulk, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Gynecare TVT™ Obturator System.

81. Defendants were negligent in failing to use reasonable care in designing, manufacturing, labeling, packaging, and selling the Gynecare TVT™ Obturator System.

82. As a direct and proximate result of Defendants' negligence, Plaintiff, Helen Foulk, was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT II: STRICT LIABILITY – DESIGN DEFECT

83. Paragraphs 1-82 of this Complaint are hereby incorporated by reference as fully set forth herein.

84. The Gynecare TVT™ Obturator System product implanted in Plaintiff, Helen Foulk was not reasonably safe for its intended use and was defective as a matter of law with respect to its design.

85. As a direct and proximate result of Defendants' negligence, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability and suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income and other damages.

86. Defendants are strictly liable to Plaintiff, Helen Foulk, for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT III: STRICT LIABILITY – MANUFACTURING DEFECT

87. Paragraphs 1-86 of this Complaint are hereby incorporated by reference as fully set forth herein.

88. The Gynecare TVT™ Obturator System product implanted in Plaintiff, Helen Foulk, was not reasonably safe for its intended use and was defective as a matter of law with respect to its manufacture.

89. As a direct and proximate result of the products' aforementioned defects, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

90. Defendants are strictly liable to Plaintiff, Helen Foulk, for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

COUNT IV: DEFECTIVE PRODUCT

91. Plaintiff incorporates by reference paragraphs 1-90 of this Complaint as if fully set forth herein.

92. The product implanted in Plaintiff, Helen Foulk, were not reasonably safe for their intended uses and were defective as described herein.

93. The Gynecare TVT™ Obturator System implanted in Plaintiff, was defective because the mesh used was not compatible with human tissue and caused harm including, but not limited to, erosion of the mesh and infection in the vagina.

94. As a direct and proximate result of the products' aforementioned defects as described herein, Plaintiff, Helen Foulk, has experienced significant mental and physical pain and suffering, has sustained stress urinary incontinence, sensory urgency, and incomplete emptying of bladder, among other symptoms.

COUNT V: STRICT LIABILITY – FAILURE TO WARN

95. Plaintiff incorporates by reference paragraphs 1-94 of this Complaint as if fully set forth herein.

96. The Gynecare TVT™ Obturator System implanted in Plaintiff, Helen Foulk, was not reasonably safe for its intended uses and was defective as a matter of law due to its lack of appropriate and necessary warnings.

97. As a direct and proximate result of the products' aforementioned defects as described herein, Plaintiff was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, or other damages.

98. Defendants are strictly liable to Plaintiff, Helen Foulk, for designing, manufacturing, marketing, labeling and selling a defective product.

COUNT VI – FRAUDULENT CONCEALMENT

99. Plaintiff incorporates by reference paragraphs 1-98 of this Complaint as if fully set forth herein.

100. At all times during the course of dealings between Defendants and Plaintiff, Helen Foulk, and/or her healthcare providers, and/or the FDA, Ethicon and Johnson & Johnson misrepresented the safety of the Gynecare TVT™ Obturator System for its intended use.

101. Defendants knew or were reckless in not knowing that their representations were false.

102. Ethicon and Johnson & Johnson were under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of the Gynecare TVT™ Obturator System including, but not limited to, the risk that the mesh can contract causing the vagina to contract and eventually perforate the vaginal wall.

103. Ethicon and Johnson & Johnson had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to the Plaintiff who was implanted with the Gynecare TVT™ Obturator System.

104. Ethicon's and Johnson & Johnson's concealment and omissions of material facts concerning, inter alia, the safety of the Gynecare TVT™ Obturator System were made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, her physicians, hospitals and healthcare providers into reliance and use of the Gynecare TVT™ Obturator System, and to cause them to purchase and/or use the Gynecare TVT™ Obturator System.

105. Ethicon and Johnson & Johnson knew that Plaintiff and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions, and that these included material omissions of fact surrounding the Gynecare TVT™ Obturator System, as set forth herein.

106. Plaintiff and her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently, and/or purposefully did not include facts that were concerns of and/or omitted by Defendants.

107. As a result of the foregoing acts and omissions, Plaintiff has suffered severe physical pain and mental anguish.

108. As a result of the foregoing acts and omissions, Plaintiff, Helen Foulk, required health care and services and incurred medical, health, incidental and related expenses.

COUNT VII: CONSTRUCTIVE FRAUD

109. Plaintiff incorporates by reference paragraphs 1-108 of this Complaint as if fully set forth herein.

110. Ethicon and Johnson & Johnson are in a unique position of knowledge concerning the quality, safety and efficacy of the Gynecare TVT™ Obturator System, which knowledge is not possessed by Plaintiff, Helen Foulk, or her physicians, and Defendants thereby hold a position of superiority over Plaintiff and her physicians.

111. Despite their unique and superior knowledge regarding the defective nature of the Gynecare TVT™ Obturator System, Ethicon and Johnson & Johnson continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Gynecare TVT™ Obturator System, as compared to other products and forms of treatment.

112. For example, scientists in a study published in *Obstetrics & Gynecology*, August 2010, found that the complication rate was so high that the clinical trial was halted early.

113. Ethicon and Johnson & Johnson have concealed and suppressed material information, including limiting clinical testing, that would reveal that the Gynecare TVT™ Obturator System had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of the products.

114. Upon information and belief, Defendants' misrepresentations are designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Defendants' Gynecare TVT™ Obturator System. Plaintiff and the medical community have relied upon Defendants' representations.

VIII: BREACH OF IMPLIED WARRANTY

115. Plaintiff incorporates by reference paragraphs 1-114 of this Complaint as if fully set forth herein.

116. Ethicon and Johnson & Johnson impliedly warranted that the Gynecare TVT™ Obturator System was merchantable and fit for the ordinary purposes for which it was intended.

117. When the Gynecare TVT™ Obturator System was implanted in the Plaintiff, Helen Foulk, to treat her pelvic organ prolapse and/or stress urinary incontinence, the products were being used for the ordinary purposes for which they were intended.

118. The Plaintiff, individually and/or by and through her physician, relied upon Defendants' implied warranties of merchantability in consenting to have the Gynecare TVT™ Obturator System implanted in her.

119. Defendants breached these implied warranties of merchantability because the Gynecare TVT™ Obturator System that was implanted in the Plaintiff was neither merchantable nor suited for the intended uses as warranted.

120. Defendants' breach of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing said Plaintiff's health and safety in jeopardy.

121. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

122. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and her medical providers and engaged in constructive fraud in their relationship with Plaintiff and her medical providers. Plaintiff reasonably relied on Defendants' representations.

123. As a proximate result of the Defendants' conduct, Plaintiff, Helen Foulk, has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT IX – NEGLIGENT MISREPRESENTATION

124. Plaintiff incorporates by reference paragraphs 1-123 of this Complaint as if fully set forth herein.

125. Ethicon and Johnson & Johnson represented that the Gynecare TVT™ Obturator System was a safe and effective method to treat stress urinary incontinence.

126. Ethicon and Johnson & Johnson made these misrepresentations and actively concealed adverse information at a time when Ethicon and Johnson & Johnson knew, or should have known, that the Gynecare TVT™ Obturator System had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Helen Foulk, her physicians and the health care industry, generally.

127. Ethicon and Johnson & Johnson negligently and/or intentionally misrepresented or omitted necessary and required information in the product labeling, promotions, and advertisements and instead labeled, promoted and advertised the product as safe and effective and understated the risks associated with the Gynecare TVT™ Obturator System.

128. The aforementioned misrepresentations were untrue and misleading.

129. Ethicon and Johnson & Johnson knew or should have known that these representations were false and made the representations with the intent that Plaintiff and/or her treating physicians would rely on them, leading to the use of the Gynecare TVT™ Obturator System.

130. At the time of Defendants' fraudulent misrepresentations, Plaintiff, Helen Foulk, and/or her treating physicians were unaware of the falsity of the statements being made and believed them to be true. Plaintiff and/or her treating physicians justifiably relied on and/or were induced by the misrepresentations and/or active concealment and relied on the absence of safety information, which Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment.

COUNT X: NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

131. Plaintiff incorporates by reference paragraphs 1-130 of this Complaint as if fully set forth herein.

132. Ethicon and Johnson & Johnson carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Gynecare TVT™ Obturator System to Plaintiff, Helen Foulk, carelessly and negligently concealed the harmful effects of the

Gynecare TVT™ Obturator System from Plaintiff, Helen Foulk, and carelessly and negligently misrepresented the quality, safety and efficacy of the Gynecare TVT™ Obturator System.

133. Plaintiff was directly impacted by Ethicon and Johnson & Johnson's carelessness and negligence, in that Plaintiff sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic losses, and other damages as a direct result of being implanted with the Gynecare TVT™ Obturator System sold and distributed by Ethicon and Johnson & Johnson and/or because of the nature of their relationship to the individual implanted with the Gynecare TVT™ Obturator System.

134. As a direct and proximate result of the Defendants' conduct, Plaintiff, Helen Foulk, has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

COUNT XI: BREACH OF EXPRESS WARRANTY

135. Plaintiff incorporates by reference paragraphs 1-134 of this Complaint as if fully set forth herein.

136. Ethicon and Johnson & Johnson made assurances to the general public, hospitals and health care professionals that the Gynecare TVT™ Obturator System was safe and reasonably fit for its intended purpose.

137. Plaintiff, Helen Foulk, and/or her health care provider chose the Gynecare TVT™ Obturator System based upon Defendants' respective warranties and representations regarding the safety and fitness of the Gynecare TVT™ Obturator.

138. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' respective express warranties and guarantees that the Gynecare TVT™ Obturator System was safe, merchantable and reasonably fit for their intended purposes.

139. Defendants breached these express warranties because the Gynecare TVT™ Obturator System implanted in Plaintiff were unreasonably dangerous and defective and not as Defendants represented.

140. Ethicon and Johnson & Johnson made assurances to the general public, hospitals and health care professionals that the Gynecare TVT™ Obturator System Mesh was safe and reasonably fit for its intended purpose.

141. Plaintiff and/or her health care provider chose the Gynecare TVT™ Obturator System Mesh based upon Defendants' warranties and representations regarding the safety and fitness of the Gynecare TVT™ Obturator System Mesh.

142. Plaintiff, individually and/or by and through her physician, reasonably relied upon Defendants' respective express warranties and guarantees that the Gynecare TVT™ Obturator System Mesh was safe, merchantable and reasonably fit for their intended purposes.

143. Defendants breached these express warranties because the Gynecare TVT™ Obturator System Mesh implanted in Plaintiff was unreasonably dangerous and defective and not as Defendants represented.

144. Defendants' breaches of express warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

145. As a direct and proximate result of Defendant's breaches of the aforementioned express warranties, Plaintiff, Helen Foulk, was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT XII: BREACH OF IMPLIED WARRANTY

146. Plaintiff incorporates by reference paragraphs 1-145 of this Complaint as if fully set forth herein.

147. Ethicon and Johnson & Johnson impliedly warranted that the Gynecare TVT™ Obturator System was merchantable and was fit for the ordinary purpose for which it was intended.

148. When the Gynecare TVT™ Obturator System was implanted in Plaintiff, Helen Foulk, to treat her for stress urinary incontinence and other symptoms, it was being used for the ordinary purposes for which it was intended.

149. Plaintiff, individually and/or by and through her physician, relied upon Ethicon's and Johnson & Johnson's implied warranties of merchantability in consenting to have the Gynecare TVT™ Obturator System implanted in her.

150. Ethicon and Johnson & Johnson breached these implied warranties of merchantability because the Gynecare TVT™ Obturator System implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted.

151. Defendants' breaches of their implied warranties resulted in the implantation of an unreasonably dangerous and defective product in Plaintiff's body, placing Plaintiff's health and safety in jeopardy.

152. As a direct and proximate result of Defendants' breaches of the aforementioned implied warranties, Plaintiff, Helen Foulk, was caused and/or in the future will be caused to suffer severe personal injuries, pain, disability, suffering, severe emotional distress, financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

COUNT XIII: GROSS NEGLIGENCE

153. Plaintiff incorporates by reference paragraphs 1-152 of this Complaint as if fully set forth herein.

154. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, Helen Foulk, for which the law would allow, and for which Plaintiff will seek at the appropriate time under governing law, the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with the applicable federal standards' was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk

involved, but nevertheless proceeded with conscious indifferences to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a perspective assertion, with the intent that the representation would be acted on by Plaintiff.

155. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

156. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

157. Plaintiff, Helen Foulk, also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

COUNT XIV: UNJUST ENRICHMENT

158. Plaintiff incorporates by reference paragraphs 1-157 of this Complaint as if fully set forth herein.

159. Plaintiff, Helen Foulk, paid for the Gynecare TVT™ Obturator System for the purpose of treatment of stress urinary incontinence and/or pelvic organ prolapse or other similar conditions.

160. Ethicon and Johnson & Johnson have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Gynecare TVT™ Obturator System.

161. Plaintiff has not received the safe and effective medical devices for which she paid.

162. It would be inequitable for Defendants to keep this money since Plaintiff, Helen Foulk, did not in fact receive a safe and effective medical device as represented by Defendants.

COUNT XV: - PUNITIVE DAMAGES

163. Plaintiff incorporates by reference paragraphs 1-162 of this Complaint as if fully set forth herein.

164. Ethicon and Johnson & Johnson knew or should have known that the Gynecare TVT™ Obturator System was defective and presented unreasonable risks of harm to Plaintiff, Helen Foulk.

165. Ethicon and Johnson & Johnson sold the Gynecare TVT™ Obturator System to Plaintiff's health care providers and other providers in Wisconsin and throughout the United States without doing adequate testing to ensure that the Gynecare TVT™ Obturator System was reasonably safe for implantation in the female pelvic area.

166. Ethicon and Johnson & Johnson sold the Gynecare TVT™ Obturator System to Plaintiff's health care providers and other health care providers in Wisconsin and throughout the United States without doing adequate testing to determine whether the Gynecare TVT™ Obturator System degraded *in vivo*. The Gynecare TVT™ Obturator System does, in fact, degrade *in vivo,* which causes the severe and debilitating injuries suffered by Plaintiff and numerous other women.

167. Ethicon and Johnson & Johnson ignored reports from health care providers throughout the United States of the Gynecare TVT™ Obturator System's failures to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to rule out the Gynecare TVT™ Obturator System's design flaws or the processes by which the Gynecare TVT™ Obturator System is manufactured as the cause of these severe and debilitating injuries, Ethicon and Johnson & Johnson chose instead to instruct its sales forces to downplay the Gynecare TVT™ Obturator System's risks, and continued to market and sell the Gynecare TVT™ Obturator System as safe and effective treatments of stress urinary incontinence.

168. The wrongs done by Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the law would allow, and for which Plaintiff will seek at the appropriate time under governing law, the imposition of exemplary damages, in that Defendants' conduct, including the failure to comply with the applicable federal standards was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct,

involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifferences to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants knowing that it was false or with reckless disregard as to its truth and as a perspective assertion, with the intent that the representation would be acted on by Plaintiff.

169. Plaintiff, Helen Foulk, therefore, will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

COUNT XVI: DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

170. Plaintiff incorporates by reference paragraphs 1-169 of this Complaint as if fully set forth herein.

171. Plaintiff, Helen Foulk, asserts all applicable state statutory and common law rights and theories related to tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

172. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of injury, and the tortious nature of the wrongdoing that caused the injury.

173. Under appropriate applications of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

174. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physician of the true risks associated with the Gynecare TVT™ Obturator System. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physician were unaware, and could not have known or have learned through reasonable diligence that

Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

i. Compensatory damages in excess of the minimum jurisdictional amount, including, but not limited to, compensation for injury, pain, suffering, mental anguish, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined by the trier of fact in this action:

ii. Economic damages in the form of medical expenses, out-of-pocket expenses, life care expenses, and other economic damages in an amount to be determined by the trier of fact in this action;

iii. Attorneys' fees, expenses, and other costs of this action;

iv. Punitive damages; and

v. Such relief as this Honorable Court deems necessary, just and proper.

PLAINTIFF DEMANDS A TRIAL BY JURY

DATED: January 11, 2019

By: /s/Bert Tarrant Dunken, Jr.
Attorney for Plaintiff
HELEN FOULK